Patent

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REMARKS

Claims 1, 5-17, 19, and 21-38 are pending in the Application. Independent claim 1 has been amended to recite the feature wherein the location of the disturbance is determined based, at least in part, on a delay time from the transmission of the ultrasound energy burst to the reception of the reflected portions of the ultrasound energy bursts from the proximally located disturbance. In light of the amendment made to claim 1, dependent claims 2-4 have been cancelled. In addition, dependent claims 5 and 10 have been amended to more clearly recite the step of analyzing a received reflection portion from the disturbance. Dependent claim has been amended to more clearly recite that one or more characteristics of the disturbance are determined.

Independent claim 17 has similarly been amended to recite the feature wherein the system configured to, inter alia, determine the location of a disturbance located in the transmission path proximal of the focal zone based, at least in part, on a delay time from the transmission of the ultrasound energy burst to the reception of the reflected portions of the ultrasound energy burst from the disturbance. Claim 17, like independent claim 1, have been amended to more clearly recite the claimed feature that the location of a proximally-disposed disturbance (proximal with respect to the focal zone) is determined at least in part on the delay time of a reflected portion of an ultrasound energy burst reflecting from the disturbance.

In light of the amendment to claim 17, dependent claims 18 and 20 have been cancelled. The dependency of claims 19, 28, and 29 has been amended to depend from claim 17. Claim 21 has been amended to more particularly recite the feature that the reflected portion (of ultrasound energy) is from the disturbance. Dependent claim 35 has been amended to recite the feature that the processor determines the range from the transducer to the disturbance that generated the reflection.

In the Office Action dated March 9, 2006, claims 1 and 17 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,844,140 (Seale). Claims 2-16, 18-31, and 33-38 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Seale, in view of U.S. Patent No. 6,042,556 (Beach et al.) and U.S. Patent No. 4,958,639 (Uchiyama et al.). Claim 32 was rejected under 35 U.S.C. § 103(a) as being unpatentable

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over <u>Seale</u>, in view of <u>Beach</u> and <u>Uchiyama</u>, and further in view of U.S. Patent No. 5,485,839 to (<u>Aida et al.</u>). The above-noted rejections are traversed in light of the amendments made to the claims herein.

Initially, <u>Seale</u> relates principally to an "AimServo" system that aligns an ultrasound beam by controlling an electromagnetically levitated rotor whose motions alter the beam path. <u>See</u> Col. 4, lines 51-53. <u>Seale</u> does not concern itself with locating or characterizing a disturbance located proximal with respect to a focal plane. Rather, the AimServo system of <u>Seale</u> uses beam path translation and rotation to image a small target area from a range of base locations, leading to a computational derivation of a high resolution image equivalent to that obtainable from an aperture of dimensions too large for practical achievement with a fixed system of ultrasound lenses and/or reflectors. Col. 5, lines 4-9. The AimServo system is also purportedly a useful tracking modality, where a time-varying parameter such as flow velocity can be determined for a small target volume in a situation where target and/or sensor position and orientation vary over time, demanding dynamic correction of the ultrasound beam path. <u>See</u> Col. 5, lines 14-18. In this regard, the AimServo system of <u>Seale</u> is useful to monitor fetal heart rate and cerebral blood flow. Col. 5, lines 19-20.

Notably absent from <u>Seale</u> is any teaching or suggestion of functionality for locating (or analyzing for that matter) a disturbance in an energy path of a focused ultrasound system. The Office Action suggests that <u>Seale</u> discloses a method and apparatus for detecting a disturbance or perturbation in a transmission path of a focused ultrasound system. <u>Seale.g.</u>, Office Action, ¶ 3. However, no such functionality is disclosed or otherwise suggested in <u>Seale</u>. To the extent that <u>Seale</u> discloses anything related to a "perturbation," <u>Seale</u> discloses that in the tracking modality, small-perturbation dither of the beam path is used to determine a direction for corrective alignment toward improved signal reception. Col. 5, lines 24-26. In other words, the small dithering of the beam path is used to improve the alignment tracking in situations where the transducer is used to track moving target volume such as blood flow.

<u>Seale</u> is simply devoid of any teaching of any method or system that locates disturbances in an energy path of a focused ultrasound system as presently claimed in

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claims 1 and 17. Because of this deficiency, <u>Seale</u> also necessarily fails to disclose or otherwise suggest the feature where the location of the disturbance is determined based, at least in part, on a delay time from the transmission of the ultrasound energy burst to the reception of the reflected portions of the ultrasound energy bursts from the proximally located disturbance. For this reason, the claims pending in the Application are not anticipated by <u>Seale</u>.

With respect to the § 103 rejections, none of the remaining cited prior art references remedy this fundamental deficiency in <u>Seale</u>. For example, the <u>Beach et al.</u> reference fails to disclose or suggest at least the claimed feature of a system (or method) that determines the location of a disturbance based, at least in part, on a delay time from the transmission of an ultrasound energy burst to the reception of the reflected portions of the ultrasound energy burst from the disturbance. In essence, the location is determined based on the time-of-flight of the ultrasound pulse from transmission to reflection *from the disturbance*. <u>Beach et al.</u> operates in an entirely different manner. Rather than measure the delay or time-of-flight of the ultrasonic pulse reflecting from a disturbance directly, the <u>Beach et al.</u> system listens for an echo that is anticipated to appear from a *target volume*. If the anticipated echo is not heard, (e.g., the amplitude falls below a threshold value within a certain time window) the <u>Beach et al.</u> system <u>merely assumes</u> that the path is blocked by an ultrasound-opaque region. This point is explicitly set forth in Col 7., lines 59-64 of the <u>Beach et al.</u>:

This is achieved by monitoring the echoes of the transmitted ultrasound burst at each active element. If the echo amplitude to that element, when gated to the target volume, is below a threshold value, then it is assumed that the path is blocked by an ultrasound-opaque region. Such elements are then deactivated. (Col. 7 lines 44 through 64) (emphasis added).

The transducer system disclosed in <u>Beach et al.</u> thus does not directly locate or identify disturbances. Instead, <u>Beach et al.</u> assumes their presence based on the observed echo signals reflecting from a target volume. Consequently <u>Beach et al.</u> fails to teach a

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device or system that utilizes time-of-flight (i.e., delay time) to directly locate a disturbance located in the path of the energy beam. At most, <u>Beach et al.</u> infers the presence of a disturbance in the beam path based on the absence of a reflected signal from a target volume.

The <u>Uchiyama et al.</u> reference is equally inapplicable to the pending claims. <u>Uchiyama et al.</u> discloses an ultrasonic therapeutical apparatus that includes a shock wave generating system that is driven to generate an ultrasonic shock wave, which is directed to a focal point, thereby crushing a calculus. <u>Uchiyama et al.</u> does not disclose a method or system for locating a disturbance in an energy path that is proximal to a focal plane.

Similarly, the <u>Aida et al.</u> reference fails to disclose or otherwise suggest at least the claimed feature where a system (or method) determines the location of a disturbance based, at least in part, on a delay time from the transmission of an ultrasound energy burst to the reception of the reflected portions of the ultrasound energy burst from the disturbance. Accordingly, even assuming that the teachings of <u>Seale</u>, <u>Beach et al.</u>, <u>Uchiyama et al.</u>, and <u>Aida et al.</u> could be combined, the resulting combination would still lack the above-noted claimed feature. For this reason, Applicant's pending claims are patentable over the cited art.

The present amendment to the claims is being made to place the same in better form for purposes of appeal, should that be necessary. Nonetheless, Applicant believes the amended claims are patentable over the cited prior art and a notice of allowability is earnestly requested. If there are any questions concerning this paper, please contact the undersigned at (408) 777-2905.

Respectfully submitted,

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